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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,637	05/25/2001	Bernard Rentier	B45082D1	4711

7590 08/19/2005

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EXAMINER	
MOSHER, MARY	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 08/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/865,637	RENTIER ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *13-19* is/are allowed.

6)☒ Claim(s) *20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/18/05*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 4/18/2005 has been entered.

Claim Rejections - 35 USC § 112

Claims 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 20-21 are drawn to a method of making an "effective pharmaceutical composition" but do not state what effect the composition is supposed to have. Since compositions for different purposes are formulated differently, the metes and bounds of the claimed method are unclear.

Claims 20-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of making an immunogenic pharmaceutical composition, does not reasonably provide enablement for the broadly claimed generic pharmaceutical composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these

claims. The specification teaches immunogenic compositions, but does not teach how to make or effectively use any other type or pharmaceutical compositions. For example, the specification does not teach how to use the IE63 in a nonimmunological gene therapy method, or how to formulate a composition for that undisclosed use. Considering the limited scope of the disclosure, the broad scope of the claim, and the undeveloped state of the art for therapeutic use of IE63, it is concluded that undue experimentation would be required to practice the full scope of the invention as claimed.

Both of the above rejections could be obviated by insertion of "immunogenic" between "effective" and "pharmaceutical" in line 1 of claim 20.

Allowable Subject Matter

Claims 13-19 are allowed. Claims 20-21 would be allowed if amended as suggested.

The following is a statement of reasons for the indication of allowable subject matter:

Debrus et al (Journal of Virology 69:3240-3245, 1995, already of record) is cited as the closest prior art. Debrus teaches a plasmid isolated from E. coli which comprises a nucleic acid encoding Varicella Zoster IE63 protein. Debrus also teaches a recombinant protein comprising VZV IE63, which is expressed in E. coli, and isolated by detergent extraction and affinity chromatography. Debrus teaches immunization of rabbits with the recombinant protein, for the purpose of obtaining antibodies to use for detecting VZV IE63. Debrus does not provide any

motivation to immunize humans. Debrus does not anticipate "method of making" claim 20 for the following reasons.

First, claim 20 requires mixing of the isolated protein or nucleic acid with "a human pharmaceutically acceptable excipient." An argument might be made that the water used in ordinary lab preparations would be a human pharmaceutically acceptable excipient. However, the United States Pharmacopeia National Formulary indicates that "purified water" is the lowest quality excipient suitable for pharmaceutical use, and that the system producing the purified water must be validated, frequently sanitized, and the water monitored for viable microorganisms and endotoxins (see as evidence USP27 NF22. The United States Pharmacopeia, The National Formulary, 2004. United States Pharmacopeial Convention, Inc., Rockville, MD. Pages 2628-2636, 1949-1951). There is no reason to believe that the water used in Debrus met these requirements.

Second, claim 20 requires production of a "safe" pharmaceutical composition. Liu et al (Clinical Biochemistry 30:455-463, 1997) is cited as evidence that recombinant proteins purified from E. coli are typically contaminated with endotoxin, which render them unsafe for pharmaceutical use. Wicks et al (Human Gene Therapy 6 (3): 317-323, abstract only cited) is cited as evidence that plasmid DNA purified from E. coli also is typically contaminated with endotoxin. Therefore, the process used by Debrus would not meet the claim requirements for producing a safe pharmaceutical composition.

It is further noted that no rejection of claims 13-19 was made on the grounds of 112, first paragraph. The claimed processes were not illustrated by a working example. However, the full structure of VZV IE63 was known prior to the invention, and process for producing pharmaceutical compositions and processes for immunizing humans were well known, therefore there was no basis for a "written description" rejection. Applicants present a evidence consistent with a theory that an immune response to the IE63 protein is involved in control of VZV latency and reactivation, in that the IE63 protein is expressed during latency in humans and healthy humans with latent VZV show both humoral and cell-mediated immunity directed at IE63. Therefore, there is more reason than not to believe applicant's assertions that inducing an immune response to isolated IE63 would be useful in treating VZV infection, whether administered before infection or after infection. There is no reason to believe that the immune response would be unsafe, since a similar response is present in healthy humans. Consequently, it was concluded that there was not adequate grounds for an enablement rejection (except for the rejection of claims 20-21 made above).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

8/18/05

MARY E. MOSHER, PH.D.
PRIMARY EXAMINER